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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,344	03/26/2001	John Richard Baker	441842000401	1139

25226 7590 05/28/2003  
MORRISON & FOERSTER LLP  
755 PAGE MILL RD  
PALO ALTO, CA 94304-1018

EXAMINER
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SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
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1651

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DATE MAILED: 05/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

## Office Action Summary

Application No.

09/818,344

Applicant(s)

Baker

Examiner

Sandra Saucier

Art Unit

1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Mar 17, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above, claim(s) 1-26 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-35 and 37-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Mar 26, 2001 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☒ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other:

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#### DETAILED ACTION

Claims 1-40 are pending. Claims 27-35, 37-40 are considered on the merits. Claims 1-26, 36 are withdrawn from consideration as being drawn to a non-elected invention.

#### *Election/Restriction*

Applicant's election of Group V without traverse in Paper No. 8 is acknowledged.

#### *Claim Rejections - 35 USC § 112*

##### INDEFINITE

Claims 27-35, 37-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 recites "conversion of a substrate to a product by fructosamine oxidase". It is unclear if fructosamine oxidase is used to measure the product formation or if the reaction to be measured is catalyzed by fructosamine oxidase. Please insert, "catalyzed" after "product".

Claim 27 might read: A method of determining fructosamine oxidase activity in a sample comprising: measuring the conversion catalyzed by fructosamine oxidase of a substrate to a product.

It is unclear what applicant means by "superoxide reaction product" or "oxygen free radical reaction product" in claims 28 and 29. It is interpreted to mean any product derived from a reaction which involves superoxide or an oxygen free radical.

Claim 30, where is the mechanism disabled? Presumably in the sample taken for the determination of fructosamine oxidase activity.

Claim 31 has no antecedent basis for "the exposure".

Claim 31 should read: to the substrate instead of "suitable fructosamine substrate".

Likewise, claim 32 should refer to "the substrate".

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-29, 34 and 35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Horiuchi *et al.* [46].

The claims are directed to a method of assaying fructosamine oxidase activity comprising measuring the conversion of a substrate to a product catalyzed by fructosamine oxidase. This encompasses measuring either the disappearance of a substrate or the appearance of a product.

The references are relied upon as explained below.

Horiuchi *et al.* disclose a method of assaying fructosyl-amino acid oxidase (E.C. 1.5.3) comprising: adding fructosyl-glycine to the oxidase in a buffer at pH 8 (p.104, Enzyme assay) and measuring glycine and glycosone and hydrogen peroxide, the products of the reaction, see Table II or measuring the disappearance of oxygen, a substrate of the reaction.

Claims 28 and 29 recite that the conversion is measured by determining a level of superoxide reaction product/oxygen free radical product. Since hydrogen peroxide is considered to be both a superoxide reaction product and an oxygen free radical reaction product, the reference is considered to meet the limitations of the claim.

***Allowable Subject Matter***

Claims 30-33, 37-40 are directed to allowable subject matter.

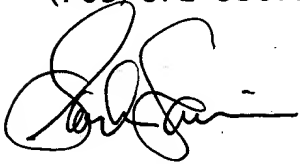
Please cancel the non-elected claims in the next response in order to facilitate allowance of the application.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday

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and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.

A handwritten signature in black ink, appearing to read 'Sandra Saucier', is positioned above the typed name.

Sandra Saucier  
Primary Examiner  
Art Unit 1651  
May 19, 2003